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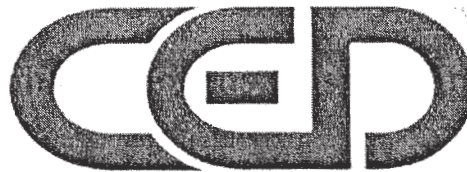
Searls v. Johns Hopkins Hospital Investigation

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CED Case No. 10707.1



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Introduction

Recently CED Technologies, Inc. (CED) was requested to perform an equipment assessment in a case involving a nursing applicant that had severe audio limitations. The Johns Hopkins Hospital (JHH) reportedly rescinded a full time employment offer to the nurse, who was requesting that she be accompanied at all times by a person able to convey all necessary information needed for her to perform her duties as a nurse via sign language.

CED was asked to examine from a human factors/biomechanical engineering perspective some of the issues that would make it impossible and or very difficult for a nurse with severe hearing problems to function on a particular floor of the JHH.

Background

Ms. Lauren O. Searls is deaf and was trained to be a nurse at the Johns Hopkins University School of Nursing. During her nursing training at JHH, Ms. Searls was provided with a full-time sign language interpreter by the School of Nursing. As a nursing student, Ms. Searls completed two clinical rotations in what is known as the Halsted 8 unit at JHH. On or about July 2012, Ms. Searls applied for a vacant position at JHH which would have required her to work full-time in the Halsted 8 unit.

Although Ms. Searls was initially offered a position in the Halsted 8 unit further evaluation by JHH indicated that she would be unable to function as a responsible nurse unless she was accompanied 100% of the time by a sign language interpreter. JHH's evaluation showed that even with the full time interpreter, Ms. Searls would have limitations that may have serious results in a hospital setting.

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JHH decided to rescind the Halsted 8 employment offer to Ms. Searls.

CED's Investigation

This case was assigned to Clyde C. Richard, Ph.D., P.E., a mechanical engineer with more than 25 years of experience in investigating various types of equipment situations. Dr. Richard has considerable experience in investigating situations where human factors issues were involved in developing a suitable design for safe use of a product. Dr. Richard was assisted in his work by Garry Brock, Ph.D., a biomechanical engineer with experience in a research hospital setting.

Dr. Richard and Dr. Brock reviewed some limited written information in this case much of which was information concerning ADA issues which were not to be a focus of their study.

On January 21, 2015 both Dr. Richard and Dr. Brock visited the JHH to meet with nursing staff to learn about the operation of the Halsted 8 unit as it existed at the time Ms. Searls was being considered for employment in this unit in 2012. Following a brief meeting, the Halsted 8 unit was made available for examination. The Halsted 8 unit was under renovation at the time of the investigation and most of the operating equipment had been removed from this section of the hospital.

It was explained that Halsted 4 was essentially a replica of Halsted 8 and was not yet renovated; operating as a medical telemetry unit. For this reason Halsted 4 was also examined in order to document various pieces of equipment and situations that would challenge a hearing impaired nurse to be able to respond to expected hospital situations without a sign language interpreter standing by her side at all times.

CED's Inspection of Halsted 8 and Halsted 4

During CED's inspection of Halsted 8, room 837A was examined. This room

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was being renovated; however, in the year 2012, this room would have been one of the locations in which Ms. Searls would have to perform her nursing duties. Within room 837A there were two emergency devices that were used routinely by a patient to call a nurse. In some cases the call could be for routine care but other times the call might be signaling a serious emergency that needed an immediate nursing response. The first device was a code machine (Figure 1). The second device was a pull cord located within the in-room lavatory (Figure 2). Both of these devices were used to signal a nurse that a situation that required immediate attention was present in the patient's room.

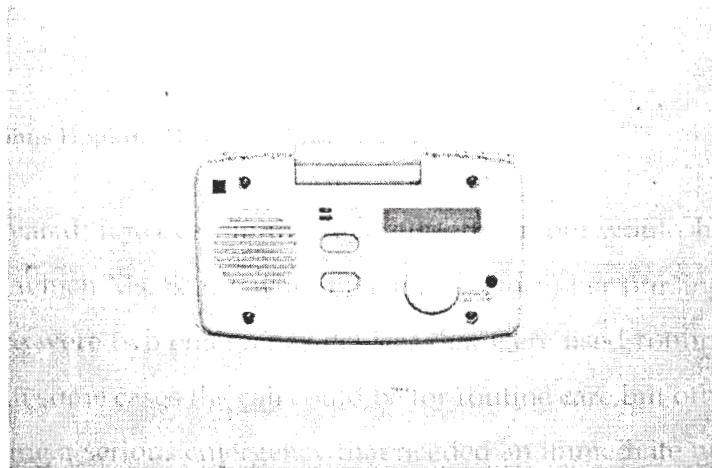


Figure 1: Code machine located within the room

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Figure 2: Emergency pull cord located within the lavatory.

The equipment in Figure 1 and Figure 2, which was located in Halsted 8, was designed to communicate to nurses through both auditory and visual signals. When the emergency equipment was activated, an auditory signal was sounded to inform nurses that an emergency situation was occurring. A light was also activated on a sign above the doorway to again inform nurses that there was a situation requiring immediate assistance (Figure 3).



Figure 3: Light monitoring system above doorways in Halsted 8

During CED's inspection, the nurse's station located within Halsted 8 was inspected. This nurse's station was located at the end of a long hallway of patient rooms located on either side of the hallway. From the nurse's station it was not possible to see the light monitoring system sign (Figure 3) located above a single patient room in the long hallway. Auditory signals therefore would be necessary to make nurses aware of a patient emergency/request. While walking through Halsted 4, which was a floor reported to be similar to Halsted 8, it was also noted that not every above-door light could be seen from the end of the hallway even if a person was not within the nurse's station, but rather standing in the hallway and looking down the hallway. Various pieces of equipment in the hallway blocked the direct view of some of the above door lights.

Although much of Halsted 8 was under renovation, the nurse's station in Halsted 8 still contained the nurse contact and call system. Upon the previously shown Code (Figure 1) or emergency pull cord (Figure 2) activation; this system would alert the nurse to a patient's need. The call system operated by an auditory

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"beep" with a signal displayed on a screen (Figure 4).



Figure 4: Call system located within the nurse's station

Equipment used in facility with audio monitoring

Patient equipment beyond the call monitoring system for Halsted 8 was no longer present. Through conversations with Maria Cvach, Assistant Director of Nursing Clinical Standards at JHH, CED was made aware of the common equipment used in Halsted 8 by the nursing staff. Operating manuals for this equipment were examined to determine the equipment functions and if auditory signals were present during use of the equipment. All of the equipment was noted to have both auditory and visual alarms during typical use. A description of the findings for a few of the pieces of equipment is shown below:

Physiologic monitor

Physiologic monitoring is necessary to measure a patient's ECG, blood pressure, and other vital patient systems. The model used at JHH in Halsted 8 was the GE Healthcare Solar 8000i. The Solar 8000i patient monitor operator's manual

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(2026264-001) stated within the warning section:

"ALARMS – Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance with correct operation of monitoring equipment." Pg. 73

CPAP/BiPAP respiratory equipment

CPAP/BiPAP equipment was used for respiratory ventilation in patients who were experiencing sleep apnea or respiratory failure. The models used at JHH were the Respironics Vison and the Respironics V60. The Respironics BiPAP Vision Ventilatory System Support manual contained a section on performance verification to ensure that the machine was working properly. Within this section, the second step stated:

"Turn the unit on. When the Test Exhalation Port/Language Screen is displayed, remove the AC power cord from the rear of the unit. Verify that the Ventilator Inoperative visual (wrench icon) and the audible alarm is activated. Turn the unit off. Verify that the audible and visual alarms are no longer active." Pg. 158

The Philips Respironics V60 Ventilator User Manual contains a section describing the principles of operation. Within this section, the statement:

"A comprehensive system of visual and audible alarms helps ensure the patient's safety. Clinical alarms can indicate an abnormal physiological condition. Technical alarms, triggered by the ventilator's self-tests, can indicate a hardware or software failure. In the case of some technical alarms, limited ventilation is provided to give the user time for corrective actions. When a condition is critical enough to possibly compromise safe ventilation, the ventilator is placed into the ventilator inoperative state, in which oxygen flow and blower operation are disabled." Pg. 31

Infusion Pump (IV and PCA)

Infusion pumps allowed for medication and nutrients to enter a patient's body

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through direct insertion into a vein. The model used at JHH in Halsted 8 was the Alaris Carefusion 8000 PCU and the Alaris Carefusion 8100 LVP. The Directions for Use: Alaris System (with Alaris PC unit, Model 8000) stated in the warning section:

“Assess patient’s condition before silencing an alarm. Do not silence alarm if patient safety might be compromised.” Pg. 1-31

Feeding pump (Kangaroo pump)

The feeding pump was an external device which transmitted the necessary nutrients to patients who were unable to feed themselves. The models used at JHH in Halsted 8 were the Zevex Infinity, Tyco Healthcare Kangaroo and Tyco Healthcare Kangaroo EPump. According to the manual, standard operation for all three of the pumps included both visual and auditory signals in the case of an alarm.

Discussion

CED was asked to complete an evaluation to determine if some of the equipment Ms. Searls would be expected to use and/or respond to during her daily work as a nurse on Halsted 8 would present difficulties for a person with auditory deficiencies. During CED’s inspection the nurse call system and emergency equipment used to monitor patient wellbeing was examined. It was noted that this equipment contained both visual and auditory signals that made nurses aware of patient situations that needed immediate attention.

The physiological monitoring system contained a monitor on which all patient information was displayed. This monitor was at the end of the hallway in the nurse’s station area. This system operated through an auditory signal consisting of a different number of “beeps” to signal an event present in one of the rooms. While one could determine alarms through watching the monitor, it would necessitate that they focus their full attention to viewing the monitor at all times. Sitting full-time in front of the monitor would prevent a nurse from completing other assigned tasks,

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ultimately impacting patient wellbeing. Signs above the doorway of patient rooms would also indicate if an emergency or patient need was ongoing. In Halsted 8, it was noted that a nurse could only see the sign above a single room from the clerk's station. An inspection of Halsted 4 indicated that it was difficult to see all of the above door signs from the end of the hallway, as equipment obscured the line of sight to some of the signs.

Individual pieces of equipment beyond the nurse call system were no longer present in Halsted 8, as this portion of the facility was under renovation. CED requested, and was given, model names and numbers for the typical equipment that would have been used by Ms. Searls as a nurse in Halsted 8. Manuals for all of the equipment indicated functionality through use of a visual and auditory alarm. The alarm would indicate an adverse event to patient health. Visual alarms were displayed on screens on the individual pieces of equipment, while audible alarms were simultaneously sounded.

Examination of the manuals for these pieces of equipment indicated that audible alarms were standard components for safe usage of this equipment. An example of the importance of audible alarms was best described by examining the Physiological monitoring equipment manual. This manual stated that having the volume low or off "may result in a hazard to the patient". The BiPAP ventilator used by JHH also stated that an auditory signal was necessary in the performance verification.

The equipment in Halsted 8 was designed and functioned under the assumption that the end user would be able to hear the auditory signals at all times. An inability to hear the alarms was a situation beyond the Halsted 8 equipment design intent. While some visual alarms were present, such as those in the nurse's station at the end of the hallway, a nurse with auditory deficiencies would have to be watching the monitor at all times to notice the visual alarm. A hard of hearing nurse

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with her back to the monitor would not be informed of a patient emergency that required immediate response. A nurse watching the monitor at all times for alarms would inhibit the ability to complete other tasks which are necessary for a nurse in Halsted 8. The inability for a nurse to respond to emergency situations which would be expected to occur numerous times during a day could affect patient safety.

Conclusions

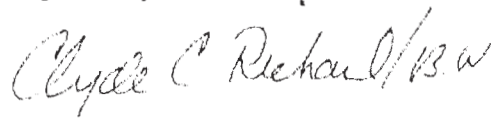
Based on an inspection of the Halsted 8 and Halsted 4 patient care units at the JHH and an investigation of some of the equipment routinely used by nurses on these units, CED is able to conclude the following, to a reasonable degree of engineering certainty:

1. In 2012 Ms. Searls was being considered for employment in the JHH unit known as Halsted 8.
2. The Nurse Call System present in Halsted 8 was designed to use both audio and visual signals to inform nurses of the need to immediately respond to patient needs.
3. A nurse lacking the ability to hear an audio signal would only be able to know that a patient was requiring attention by sitting full time in front of a monitor in the nurse's station.
4. Sitting full time in front of a monitor in the nurse's station on Halsted 8 would limit a nurse's ability to provide for patient care.
5. Several pieces of equipment that would have to be regularly used by Ms. Searls on Halsted 8 were designed with both auditory and visual alarms to indicate a change in patient status.
6. Much of the equipment used for patient care in Halsted 8 was designed and functioned under the assumption that the end user could respond to an auditory signal and/or alarm.

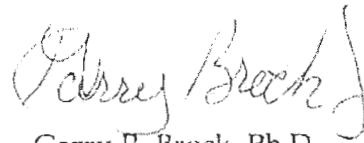
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7. Because of her audio limitations, Ms. Searls without having a full time skilled sign language interpreter standing by her side at all times, would have serious problems operating as an effective nurse on Halsted 8.

Respectfully submitted:

Handwritten signature of Clyde C. Richard in cursive script.

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